UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: September 6, 2022

SUBJECT: Efficacy Review for Jaguar 5,
EPA Reg. No. 92082-G
Action Code Case: 00350799
E-submission No. 74249

FROM: Nicole Karikari
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: September 6, 2022

THRU: Thao Pham
Efficacy Branch
Antimicrobials Division (7510M)
Date Signed: September 6, 2022

TO: John Hebert, Chief/ Emilia Oiguenblik, RM 31
Regulatory Management Branch I
Antimicrobials Division (7510M)

APPLICANT: SRFC Bio, Inc.
4460 Spring Valley Rd
Farmers Branch, TX 75244

Formulation from the Label:

Active Ingredient(s)	% by wt.
n-Alkyl dimethyl benzyl ammonium chloride (50%C14, 40% C12, 10% C16)	0.16%
Didecyl dimethyl ammonium chloride	0.24%
Other Ingredients	99.60%
Total	100.00%

I. BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Trigger Spray

Submission type: New Registration

Currently registered efficacy claim(s): N/A

Requested action(s): Applicant is submitting efficacy data to support a new product registration with hard, nonporous surface claims as a disinfectant (bactericidal, virucidal), non-food contact sanitizer, and residual self-sanitizing product.

Documents considered in this review:

- Cover letter from applicant to EPA dated 3/29/2022
- Proposed label dated 3/29/2022; Amended version dated 6/3/2022
- Data Matrix (EPA Form 8570-35) dated 3/29/2022
- Eleven efficacy studies
    - MRID 51874411
    - MRID 51874412
    - MRID 51874413
    - MRID 51874414
    - MRID 51874415
    - MRID 51874416
    - MRID 51874417
    - MRID 51874418
    - MRID 51874419
    - MRID 51874420; replaced by amended version MRID 51929701
    - MRID 51874421; replaced by amended version MRID 51929702
- Confidential Statement of Formula (EPA Form 8670-4)
    - Basic Formulation dated 3/29/2022
    - Alternate Formulations dated 3/29/2022

Submission Summary

In the Efficacy Technical Screen for the subject product, dated May 26, 2022, the Agency noted the following submission deficiencies:

1. The applicant should have the test laboratory specify the dates (Days 1-3) for the abrasion and re-inoculation procedures described in MRIDs 51874420 and 51874421.
2. As data for Influenza A (H1N1) virus, A/PR/8/34 strain (ATCC VR-1469), and Human coronavirus, 229E strain (ATCC VR-740), do not support emerging viral pathogens claims (EVP), the EVP claims on the proposed label should be removed. The subject product does not meet the eligibility criteria for EVP claims (per EVP guidance: https://www.epa.gov/pesticide-registration/emerging-viral-pathogen-guidance-and-status-antimicrobial-pesticides). However, the data for Human coronavirus will be considered for the inclusion of the subject product onto List N (per List N guidance: https://www.epa.gov/pesticide-registration/instructions-review-pesticide-registration-improvement-act-pria-submissions).

On June 9, 2022, the Applicant submitted the following response:

ACTA® ASIA | EUROPE | THE AMERICAS

June 9, 2022

Via CDX

Kathryn V. Montague (PM 31)
c/o Document Processing Desk (REGFEE)
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: Response to Technical Screening Results of Jaguar 5, EPA File Symbol: 92082-G, Action Case Number: 00350799

Dear Ms. Montague:

On behalf of SRFC Bio, Inc. (SRFC), The Acta Group (Acta®) is pleased to respond to your letter dated May 27, 2022, requesting test laboratory to specify dates for the abrasion and re-inoculation procedures described in Master Record Identification Numbers (MRIDs) 51874420 and 51874421, and to delete the Emerging Viral Pathogens (EVP) claims from the proposed product label. We wish to note that new MRIDs for the two amended reports are assigned, and the new MRIDs 51929701 and 51929702 replace the original MRIDs 51874420 and 51874421 submitted in March 2022, respectively.

This submission constitutes a complete response to EPA's letter and is submitted within the required 10-business day response window.

Accompanying this letter are the following documents:

- Transmittal Document;
- Revised Proposed label, Redline and Clean; and
- Volumes 1 to 2

If there are any questions regarding this registration application, please contact either me at mzhuang@actagroup.com or (202) 557-3819, or Gavri Grossman at gavri@srfcbio.com or (214) 257-8879.

Sincerely,

Meibao Zhuang, Ph.D.
Senior Scientist/Regulatory Consultant

Attachments

II. AGENCY STANDARDS FOR PROPOSED CLAIMS

Agency Standards for Making Viral Emerging Pathogen Claims in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels*:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, non-porous surfaces.
2. The currently accepted product label should have disinfectant efficacy claims against at least one of the following viral pathogen groupings:

For an emerging viral pathogen that is a/an…	*Qualifying criterion*
Enveloped virus emerging viral pathogen	At least one large OR one small non-enveloped virus
Large, non-enveloped emerging viral pathogen	At least one small, non-enveloped virus
Small, non-enveloped emerging viral pathogen	At least two small, non-enveloped viruses with each from a different viral family

III. PROPOSED DIRECTIONS FOR USE

"**To Disinfect:** Hold spray bottle 8"- 10" from the surface and spray until uniformly and thoroughly wet. Allow to surface to remain visibly wet for 10 minutes. Allow to air dry or wipe with a clean [cloth] [paper towel]. [Kills] [Destroys] [Effective against] [*insert organism[s] from Table 4*]

To Sanitize: Hold spray bottle 8"- 10" from the surface and spray until uniformly and thoroughly wet. Allow to surface to remain visibly wet for 5 minutes. Allow to air dry or wipe with a clean [cloth] [paper towel]. [Kills] [Reduces] [Effective against] [*insert organism[s] from Table 5*]

For [Residual] [24-hour] Sanitization: Hold spray bottle 8"- 10" from the surface and spray until uniformly and thoroughly wet. Allow to air dry. Surfaces should be visibly dry before handling. [Kills] [Reduces] [Effective against] [*insert organism[s] from Table 6*] [for 24 hours]. Preclean visibly soiled surfaces

For use as a bacteriostatic, fungistatic, and algaestatic agent to control stain and odor causing organisms on hard surfaces: Hold spray bottle 8"- 10" from the surface and spray until uniformly and thoroughly wet. Allow to air dry or wipe with a clean [cloth] [paper towel]. Surfaces should be visibly dry before handling. Preclean visibly soiled surfaces.

For use as a bacteriostatic, fungistatic, and algaestatic agent to control stain and odor causing organisms on soft surfaces: Hold spray bottle 8"- 10" from the surface and spray until wet, do not saturate. Allow to air dry. Preclean visibly soiled surfaces."

IV. STUDY SUMMARIES

1.	**MRID**	51874411		
Study Objective		Disinfectant – Bactericidal		
Study Title		AOAC Germicidal Spray Products Test		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2952-A1		
Experimental Start Date		2/22/2022	**Study Completion Date:** **Amended Report Date:**	3/7/2022 3/25/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Salmonella enterica* (ATCC 10708)		
Test Method		AOAC 961.02 – Germicidal Spray Products as Disinfectants. Revised 2013; Protocol Number: P3654		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
Test Substance Preparation	**Name/ID**	Jaguar 5		
	Lots **☐ 1 ☐ 2 ☒ 3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%] 122110J5-LCL [Total Quat: 0.360%]		
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A		
Soil load		5% Fetal Bovine Serum (FBS)		
Carrier type, # per lot		18 mm x 36 mm glass slide; 60 carriers per lot		
Test conditions		Contact time: 9 minutes 30 seconds Temperature: 21.9 – 23.1°C		

	Relative humidity: 47.5 – 51.6%
Neutralizer	Letheen Broth with 0.2% Lecithin and 0.2% Tween 80 (20.0 ml)
Incubation conditions	35.8 – 36.0°C for 46 hours 29 minutes
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Testing Synopsis: "On [February 2, 2022], testing was interrupted and material were not incubated as a sterility failure was identified on the carrier lot to be used in testing. Testing was successfully repeated on [February 22, 2022]." Protocol Amendment: "The signed protocol (P3654) was hereby amended to correct typographical error in the Success Criteria section statement concerning the viability control. The correct statement should read "The viability control subculture/neutralization broth demonstrates growth." This correction aligns with Microchem's internal SOP and the original method success criteria." No Protocol Deviations were reported. Note: In the Test Microorganism Purity Control: "Five contaminant colonies observed. Four colonies observed in lawn-type growth and one colony observed in isolated colonies on the purity streak. Morphology: raised, round, smooth, yellow. Colonies in lawn-type growth were smaller than the isolated colony." "It is the Study Director's opinion that the contamination observed was sporadic and most likely introduced at the time of plating. It was determined that the test system was not compromised or contaminated as the contamination was not present everywhere in the test, and any low level contamination would be heavily observed on the purity streak and throughout the test."

2.	**MRID**	51874412		
Study Objective		Disinfectant – Bactericidal		
Study Title		AOAC Germicidal Spray Products Test		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2950		
Experimental Start Date		2/2/2022	**Study Completion Date:**	3/2/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Pseudomonas aeruginosa* (ATCC 15442)		
Test Method		AOAC 961.02 – Germicidal Spray Products as Disinfectants. Revised 2013; Protocol Number: P3652		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
Test Substance Preparation	**Name/ID**	Jaguar 5		
	Lots **☐ 1 ☐ 2 ☒ 3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%] 122110J5-LCL [Total Quat: 0.360%]		
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use		

		Diluent: N/A
Soil load		5% Fetal Bovine Serum (FBS)
Carrier type, # per lot		18 mm x 36 mm glass slide; 60 carriers per lot
Test conditions		Contact time: 9 minutes 30 seconds Temperature: 22.1 – 22.5°C Relative humidity: 50.3 – 52.1%
Neutralizer		Letheen Broth with 0.2% Lecithin and 0.2% Tween 80 (20.0 ml)
Incubation conditions		35.5 – 35.7°C for 46 hours 30 minutes
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Testing Synopsis: "Testing for lots 122108J5-LCL, 122109J5-LCL, and 122110J5-LCL performed on [February 2, 2022] demonstrated widespread contamination, resulting in the study being repeated. This repeat was performed for all lots on [February 16, 2022], producing valid results that can be found in the Results section of this report." "The invalid results for testing performed on [February 2, 2022], including Gram staining results can be found in the Appendix section of this report." Protocol Amendment: "The signed protocol (P3654) was hereby amended to correct typographical error in the Success Criteria section statement concerning the viability control. The correct statement should read "The viability control subculture/neutralization broth demonstrates growth." This correction aligns with Microchem's internal SOP and the original method success criteria." Protocol Deviations: "On [February 16, 2022], a deviation occurred wherein the pre carrier were inadvertently vortex mixed for longer than 60 seconds. The total vortex time was 2 minutes as timed with a calibrated timer. This deviation caused by the additional vortex mixing time does not have an impact to the study as the survivability of the microorganism is not compromised by the longer time. Additionally, the longer vortexing time does not enhance the recover as the same surviving microorganisms would be removed from the carrier at 60 seconds as well as 2 minutes." "An intentional deviation occurred when performing the initial culture transfer wherein AOAC Nutrient Broth was used instead of the protocol specified AOAC Synthetic Broth. The protocol had a typographical error stating Synthetic Broth instead of Nutrient Broth for the initial transfer of microorganisms outlined throughout the Preparation of Test Culture Section. There is not impact to the study as this was performed to ensure the appropriate and optimal growth conditions for the microorganism."

3.	**MRID**	51874413
Study Objective		Disinfectant – Bactericidal

Study Title		AOAC Germicidal Spray Products Test		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2951		
Experimental Start Date		2/1/2022	**Study Completion Date:**	3/2/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Staphylococcus aureus* (ATCC 6538)		
Test Method		AOAC 961.02 – Germicidal Spray Products as Disinfectants. Revised 2013; Protocol Number: P3653		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
Test Substance Preparation	**Name/ID**	Jaguar 5		
	Lots **☐ 1 ☐ 2 ☒ 3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%] 122110J5-LCL [Total Quat: 0.360%]		
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A		
Soil load		5% Fetal Bovine Serum (FBS)		
Carrier type, # per lot		18 mm x 36 mm glass slide; 60 carriers per lot		
Test conditions		Contact time: 9 minutes 30 seconds Temperature: 22.1 – 23.0°C Relative humidity: 50.3 – 51.7%		
Neutralizer		Letheen Broth with 0.2% Lecithin and 0.2% Tween 80 (20.0 ml)		
Incubation conditions		36.0°C for 46 hours 6 minutes		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Testing Synopsis: “Testing for lots 122108J5-LCL, 122109J5-LCL, and 122110J5-LCL performed on [February 2, 2022] demonstrated widespread contamination, resulting in the study bein repeated. This repeat was performed for all lots on [February 16, 2022], producing valid results that can be found in the Results section of this report.” “The invalid results for testing performed on [February 1, 2022], including Gram staining results can be found in the Appendix section of this report.” Protocol Amendment: “The signed protocol (P3653) was hereby amended to correct typographical error in the Success Criteria section statement concerning the viability control. The correct statement should read “The viability control subculture/neutralization broth demonstrates growth.” This correction aligns with Microchem’s internal SOP and the original method success criteria.” No Protocol Deviations were reported.		

4.	**MRID**	51874414		
Study Objective		Disinfectant – Bactericidal		
Study Title		AOAC Germicidal Spray Products Test		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2969		
Experimental Start Date		3/2/2022	**Study Completion Date:**	3/10/2022
Test organism(s)		*Escherichia coli* O157:H7 (ATCC 35150)		

☒ 1 ☐ 2 ☐ 3 ☐ 4+		
Test Method		AOAC 961.02 – Germicidal Spray Products as Disinfectants. Revised 2013; Protocol Number: P3655
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle
Test Substance Preparation	**Name/ID**	Jaguar 5
	Lots ☐ 1 ☒ 2 ☐ 3	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%]
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A
Soil load		5% Fetal Bovine Serum (FBS)
Carrier type, # per lot		18 mm x 36 mm glass slide; 10 carriers per lot
Test conditions		Contact time: 9 minutes 30 seconds Temperature: 23.7 – 23.9°C Relative humidity: 29%
Neutralizer		Letheen Broth with 0.2% Lecithin and 0.2% Tween 80 (20.0 ml)
Incubation conditions		35.7°C for 46 hours 11 minutes
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendment: 1. "The signed protocol was amended to correct a typographical error in the Success Criteria section statement concerning the viability control. The correct statement should read "The viability control subculture/neutralization broth demonstrates growth." This correction aligns with Microchem's internal SOP and the original method success criteria." 2. "The signed protocol (P3655) was amended at the discretion of the Study Director, to remove the Neutralization Confirmation Log Difference equation from the Calculation Section. This change was made in that this equation was not applicable to the method performed." No Protocol Deviations were reported.

5.	**MRID**	51874415		
Study Objective		Disinfectant – Bactericidal		
Study Title		AOAC Germicidal Spray Products Test		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2968		
Experimental Start Date		3/1/2022	**Study Completion Date:**	3/25/2022
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592)		
Test Method		AOAC 961.02 – Germicidal Spray Products as Disinfectants. Revised 2013; Protocol Number: P3656		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
	Name/ID	Jaguar 5		
	Lots	122108J5-LCL [Total Quat: 0.360%]		

Test Substance Preparation	**☐ 1 ☒ 2 ☐ 3**	122109J5-LCL [Total Quat: 0.363%]
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A
Soil load		5% Fetal Bovine Serum (FBS)
Carrier type, # per lot		18 mm x 36 mm glass slide; 10 carriers per lot
Test conditions		Contact time: 9 minutes 30 seconds Temperature: 22.9 – 23.4°C Relative humidity: 28 – 29%
Neutralizer		Letheen Broth with 0.2% Lecithin and 0.2% Tween 80 (20.0 ml)
Incubation conditions		36.1 – 36.2°C for 46 hours 47 minutes
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendment: 1. "The signed protocol was amended to correct a typographical error in the Success Criteria section statement concerning the viability control. The correct statement should read "The viability control subculture/neutralization broth demonstrates growth." This correction aligns with Microchem's internal SOP and the original method success criteria." 2. "The signed protocol (P3655) was amended at the discretion of the Study Director, to remove the Neutralization Confirmation Log Difference equation from the Calculation Section. This change was made in that this equation was not applicable to the method performed." 3. "The signed protocol (P3656) is hereby amended, at the discretion of the Study Director, to clarify the reference section as follows: "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, product Performance Test Guidelines OCSPP 810.2200: General Consideration for Testing Public Health Pesticides – Guidance for Efficacy Testing. February 2018." Amended to: "U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, product Performance Test Guidelines OCSPP 810.2000: General Consideration for Testing Public Health Pesticides – Guidance for Efficacy Testing. February 2018." No Protocol Deviations were reported.

6.	**MRID**	51874416
Study Objective		Disinfectant – Virucidal
Study Title		Virucidal Efficacy of a Test Substance for use on Inanimate, Nonporous Surfaces
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2971

Experimental Start Date		3/2/2022	**Study Completion Date:**	3/22/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Influenza A (H1N1) virus, A/PR/8/34 strain (ATCC VR-1469)		
Indicator Cell Culture		MDCK cells (NCL-2) (ATCC CCL-34)		
Test Method		ASTM E1053 – Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces; Protocol Number: P3662		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
Test Substance Preparation	**Name/ID**	Jaguar 5		
	Lots **☐ 1 ☒ 2 ☐ 3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%]		
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A		
Soil load		5% Fetal Bovine Serum (FBS)		
Carrier type, # per lot		Sterile glass Petri dish (100 mm x 15 mm); 1 carrier per lot		
Test conditions		Contact time: 9 minutes 30 seconds Temperature: 23.4 – 23.9°C Relative humidity: 40.7 – 41.7%		
Neutralizer		10% Eagle's Minimum Essential Medium (EMEM) supplemented with 0.3% sodium thiosulfate and 0.1% lecithin; Sephadex LH-20 gel filtration column		
Incubation conditions		36±2°C in a humidified atmosphere of 6±1% CO_2		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No Protocol Amendments or Protocol Deviations were reported.		

7.	**MRID**	51874417		
Study Objective		Disinfectant – Virucidal		
Study Title		Virucidal Efficacy of a Test Substance for use on Inanimate, Nonporous Surfaces		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2970		
Experimental Start Date		3/2/2022	**Study Completion Date:**	3/22/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Human coronavirus, 229E strain (ATCC VR-740)		
Indicator Cell Culture		MRC-5 cells (ATCC CCL-171)		
Test Method		ASTM E1053 – Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces; Protocol Number: P3661		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
Test Substance Preparation	**Name/ID**	Jaguar 5		
	Lots **☐ 1 ☒ 2 ☐ 3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%]		
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use		

		Diluent: N/A
Soil load		5% Fetal Bovine Serum (FBS)
Carrier type, # per lot		Sterile glass Petri dish (100 mm x 15 mm); 1 carrier per lot
Test conditions		Contact time: 9 minutes 30 seconds Temperature: 24.0 – 24.2°C Relative humidity: 37.0 – 37.2%
Neutralizer		10% Eagle's Minimum Essential Medium (EMEM) supplemented with 0.3% sodium thiosulfate and 0.1% lecithin; Sephadex LH-20 gel filtration column
Incubation conditions		33±2°C in a humidified atmosphere of 6±1% CO_2
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No Protocol Amendments or Protocol Deviations were reported.

8.	**MRID**	51874418		
Study Objective		Non-Food Contact Sanitizer		
Study Title		Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces via Spray Application		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2954		
Experimental Start Date		2/9/2022	**Study Completion Date:**	2/25/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Staphylococcus aureus* (ATCC 6538)		
Test Method		ASTM E1153 – Standard Test Method for Efficacy of Sanitizer Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces; Protocol Number: P3657		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
Test Substance Preparation	**Name/ID**	Jaguar 5		
	Lots **☐ 1 ☐ 2 ☒ 3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%] 122110J5-LCL [Total Quat: 0.360%]		
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A		
Soil load		5% Fetal Bovine Serum (FBS)		
Carrier type, # per lot		18 mm x 36 mm glass slide; 5 carriers per lot		
Test conditions		Contact time: 4 minutes 30 seconds Temperature: 24.6 – 26.4°C Relative humidity: 32 – 34%		
Neutralizer		DE Broth (20.0 ml)		
Incubation conditions		36.0°C for 44 hours 23 minutes		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No Protocol Amendments or Protocol Deviations were reported. Note, controls and test resulted in sporadic, isolated contamination. The Study Director determined that these did not impede plate reading nor the validity of the study.		

9.	**MRID**	51874419		
Study Objective		Non-Food Contact Sanitizer		
Study Title		Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces via Spray Application		
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2955		
Experimental Start Date		2/10/2022	**Study Completion Date:**	2/25/2022
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Klebsiella aerogenes* (ATCC 13048)		
Test Method		ASTM E1153 – Standard Test Method for Efficacy of Sanitizer Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces; Protocol Number: P3658		
Application Method		Trigger spray; sprayed two times at a distance of 8-10 inches and ~45° angle		
Test Substance Preparation	**Name/ID**	Jaguar 5		
	Lots **☐ 1 ☐ 2 ☒ 3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%] 122110J5-LCL [Total Quat: 0.360%]		
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A		
Soil load		5% Fetal Bovine Serum (FBS)		
Carrier type, # per lot		18 mm x 36 mm glass slide; 5 carriers per lot		
Test conditions		Contact time: 4 minutes 30 seconds Temperature: 23.9 – 24.1°C Relative humidity: 34 – 36%		
Neutralizer		DE Broth (20.0 ml)		
Incubation conditions		29.0 – 29.2°C for 46 hours 3 minutes		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No Protocol Amendments were reported. Protocol Deviation: “A deviation occurred on [February 10, 2022] wherein during neutralization of efficacy carrier, for the last carrier for Lot: 122110J5-LCL, the remaining liquid from the Petri dish was not added to the jar as the dish was inadvertently discarded prior to aspiration of the excess liquid.” “Per the raw data, the documented volume recovered from the efficacy testing carriers at the time of test was approximately 1 ml. It was determined by the Study Director that this volume is negligible in the total recovered volume at the time of performing calculations, therefore, this deviation does not have an impact on the study.” Note: A single surface contaminant was noted in the carrier sterility control and the culture diluent sterility control. Carrier sterility control – “Morphology: cream and pale yellow, raised mucoid, irregular edges. Small foreign body (hair-like) observed under colony.” Culture diluent Sterility Control – “Morphology: cream, raised mucoid, round.”		

	"Based on the colony morphology and Gram stain results, it was determined that the surface contaminants present in the carrier and diluent sterility control plates were sporadic, isolated occurrences and not a systemic problem. They did not interfere with the reading of results and have not impact to the validity and quality of the study."

10.	**MRID**	51929701			
Study Objective		Residual Sanitizer			
Study Title		Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Nonporous Surfaces			
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2960-A1			
Experimental Start Date		2/21/2022	**Study Completion Date:**	3/25/2022	
			Report Amended Date:	6/8/2022	
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Staphylococcus aureus* (ATCC 6538)			
Test Method		US EPA Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Nonporous Surfaces; Protocol Number: P3659			
Application Method		Trigger spray; sprayed using a 3 second hold at a distance of 8-10 inches and ~60° angle (See Protocol Deviations below.)			
Test Substance Preparation	**Name/ID**	Jaguar 5			
	Lots ☐ **1** ☐ **2** ☒ **3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%] 122110J5-LCL [Total Quat: 0.360%]			
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A			
Soil load		5% Fetal Bovine Serum (FBS)			
Carrier type, # per lot		1" x 1" glass slide; 4 carriers per lot			
Test conditions		Contact time: 5 minutes			
		Description:	Temperature:	Relative humidity:	
		Test Substance Drying Conditions	22.6 – 24.1°C	48.4 – 51.9%	
		Abrasion Conditions	21.4 – 23.2°C	28.8 – 52.0%	
		Final Efficacy Conditions	20.1 – 20.9°C	30.2 – 30.6%	
Neutralizer		Dey-Engley (DE) Broth (30.0 ml)			
Incubation conditions		Day 1	35.7°C for 48 hours 29 minutes		
		Day 2	35.4 – 35.7°C for 49 hours 9 minutes		
		Day 3	35.7 – 35.8°C for 48 hours 18 minutes		
		Day 4	35.8 – 35.9°C for 48 hours 8 minutes		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. "The signed protocol (P3659) is hereby amended to allow the use of conicals or other sterile vessels as well as sterile jars for the harvesting/recovery of the carriers into neutralizing broth throughout the performance of the study. The change was made at the discretion of the Study			

	Director to ensure efficiency and aseptic handling at the time of use." 2. "The signed protocol (P3659) is hereby amended to clarify the study purpose and remove the statement "residual self-disinfection" and replace with "residual self-sanitizing". This change is made to include the applicable and relevant information regarding Residual Self Sanitization." Protocol Deviations: "On [February 24, 2022], a deviation occurred wherein the organic soil sterility was inadvertently not performed on the day of "Final Efficacy Determination". The organic soil load sterility is performed to ensure the sterility of the soil used in testing. It was determined that there is no impact to the study as the same lot of soil used in the final efficacy inoculum was used in previous dates testing on [February 21, 2022] and [February 22, 2022] and sterility plates for both days showed no growth. Additionally, no contamination was observed during the reading of results that would indicate any contamination of the organic soil." "On [February 23, 2022], a deviation occurred wherein the relative humidity was inadvertently outside the protocol specified range of "30-55%" during abrasion wear cycles 6-11 for the test and control carriers. It was determined that this deviation does not have an impact on the study in that the humidity during these cycles was less than 2% lower from the minimum value when outside of the range. The humidity control is important to ensure the microorganism, survival during the drying period. These wear cycles did not involve any reinoculation and the appropriate waiting period for carriers to sit at ambient temp was followed (at least 15 minutes). "During the treatment of the control carriers with the control substance, an intentional deviation occurred wherein a 3 second hold of the Preval spray bottle was used to treat, as opposed to the 2 sprays in Sponsor's request. This deviation was intentional at the discretion of the Study Director. This deviation took place due to the spray bottle for test substance application and the spray bottle for the control substance using 2 sprays." "A small troubleshoot was performed to demonstrate a sufficient coverage of the carriers and a 3 second hold demonstrated an equivalent volume delivered as the Flairosol spray bottles based on the volume recovered from an empty Petri dish (1.3 ml on average). This alternate application demonstrated to sufficiently cover the carrier and therefore there is no impact to the study."

11.	**MRID**	51929702			
Study Objective		Residual Sanitizer			
Study Title		Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Nonporous Surfaces			
Testing Lab; Lab Study ID		Microchem Laboratory; GLP2972-A1			
Experimental Start Date		3/8/2022	**Study Completion Date:**	3/25/2022	
			Report Amended Date:	6/8/2022	
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Klebsiella aerogenes* (ATCC 13048)			
Test Method		US EPA Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Nonporous Surfaces; Protocol Number: P3660			
Application Method		Trigger spray; sprayed using a 3 second hold at a distance of 8-10 inches and ~60° angle (See Protocol Deviations below.)			
Test Substance Preparation	**Name/ID**	Jaguar 5			
	Lots ☐ **1** ☐ **2** ☒ **3**	122108J5-LCL [Total Quat: 0.360%] 122109J5-LCL [Total Quat: 0.363%] 122110J5-LCL [Total Quat: 0.360%]			
	Preparation	Tested concentration: LCL Tested Dilution: Ready-to-use Diluent: N/A			
Soil load		5% Fetal Bovine Serum (FBS)			
Carrier type, # per lot		1” x 1” glass slide; 4 carriers per lot			
Test conditions		Contact time: 5 minutes			
		Description:	Temperature:	Relative humidity:	
		Test Substance Drying Conditions	21.9 – 23.4°C	36 – 37%	
		Abrasion Conditions	20.8 – 23.7°C	33 – 39%	
		Final Efficacy Conditions	22.0 – 22.4°C	33 – 34%	
Neutralizer		Dey-Engley (DE) Broth (30.0 ml)			
Incubation conditions		Day 1	28.4 – 29.3°C for 48 hours 18 minutes		
		Day 2	28.5 – 28.7°C for 48 hours 3 minutes		
		Day 3	28.4 – 29.1°C for 48 hours 50 minutes		
		Day 4	28.2 – 29.1°C for 49 hours 19 minutes		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendments: 1. “The signed protocol (P3660) is hereby amended to allow the use of conicals or other sterile vessels as well as sterile jars for the harvesting/recovery of the carriers into neutralizing broth throughout the performance of the study. The change was made at the discretion of the Study Director to ensure efficiency and aseptic handling at the time of use.” 2. “The signed protocol (P3660) is hereby amended to clarify the study purpose and remove the statement “residual self-disinfection” and replace with “residual self-sanitizing”. This change is made to include the applicable and relevant information regarding Residual Self Sanitization.”			

	Protocol Deviations: “During the treatment of the control carriers with the control substance, an intentional deviation occurred wherein a 3 second hold of the Preval spray bottle was used to treat, as opposed to the 2 sprays in Sponsor’s request. This deviation was intentional at the discretion of the Study Director. This deviation took place due to the spray bottle for test substance application and the spray bottle for the control substance using 2 sprays. A small troubleshoot was performed to demonstrate a sufficient coverage of the carriers and a 3 second hold demonstrated an equivalent volume delivered as the Flairosol spray bottles based on the volume recovered from an empty Petri dish (1.3 ml on average). This alternate application demonstrated to sufficiently cover the carrier and therefore there is no impact to the study.”

V. STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	Organism	Test Date	Results		Population Control Average Log_{10} CFU/ carrier
			Lot No.	No. Exhibiting Growth/ Total No. Tested	
Ready-to-use trigger spray, 9 minutes 30 seconds, 5% soil load present					
51874411	*Salmonella enterica* (ATCC 10708)	2/22/2022	122108J5-LCL	0/60	4.70
			122109J5-LCL	0/60	
			122110J5-LCL	0/60	
51874412	*Pseudomonas aeruginosa* (ATCC 15442)	2/2/2022	122108J5-LCL	60/60*contaminants	5.69
			122109J5-LCL	60/60*contaminants	
			122110J5-LCL	60/60*contaminants	
		2/16/2022	122108J5-LCL	0/60	6.95
			122109J5-LCL	0/60	
			122110J5-LCL	0/60	
51874413	*Staphylococcus aureus* (ATCC 6538)	2/1/2022	122108J5-LCL	40/60	6.19
			122109J5-LCL	38/60	
			122110J5-LCL	52/60	
		2/16/2022	122108J5-LCL	0/60	6.11
			122109J5-LCL	0/60	
			122110J5-LCL	0/60	
51874414	*Escherichia coli* O157:H7 (ATCC 35150)	3/2/2022	122108J5-LCL	0/10	5.40
			122109J5-LCL	0/10	
51874415	Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592)	3/1/2022	122108J5-LCL	0/10	4.71
			122109J5-LCL	0/10	

Antibiotic Resistance Assay

MRID	Organism	Description	Dilution Assayed	Inoculum Concentration	Antibiotic Disk	Zone of Inhibition Observed*	CLSI M100 Zone Interpretation Criteria*	Result
51874415	Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592)	Test organism	Raw	1.21 x 10^8 CFU/ml	Cefoxitin (30 µg)	≤ 6 mm	Resistance: ≤ 21 mm	Resistant
	Staphylococcus aureus (ATCC 25923)	Reference organism	Resuspended Undiluted	1.47 x 10^8 CFU/ml	Cefoxitin (30 µg)	25 mm	Susceptible: ≥ 22 mm	Susceptible

*Zone diameter (mm)

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/ carrier)
Ready-to-use trigger spray, 9 minutes 30 seconds, 5% soil load present					
51874416	Influenza A (H1N1) virus, A/PR/8/34 strain (ATCC VR-1469)	Lot No.	122108J5-LCL	122109J5-LCL	6.30
		10^{-1} dilution	Cytotoxicity (4/4)	Cytotoxicity (4/4)	
		10^{-2} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/ 100 µl	≤ 1.50	≤ 1.50	
		Log_{10} $TCID_{50}$/ carrier	≤ 1.80	≤ 1.80	
		Log Reduction	≥ 4.50	≥ 4.50	
51874417	Human coronavirus, 229E strain (ATCC VR-740)	Lot No.	122108J5-LCL	122109J5-LCL	5.55
		10^{-1} dilution	Cytotoxicity (4/4)	Cytotoxicity (4/4)	
		10^{-2} to 10^{-6} dilution	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/ 100 µl	≤ 1.50	≤ 1.50	
		Log_{10} $TCID_{50}$/ carrier	≤ 1.80	≤ 1.80	
		Log Reduction	≥ 3.75	≥ 3.75	

Non-Food Contact Sanitizer

MRID	Organism	Results			Population Control Average Log_{10} CFU/ carrier (Geometric Mean)
		Lot No.	Average Log_{10} CFU/ Carrier	Percent Reduction	
Ready-to-use trigger spray, 4 minutes 30 seconds, 5% soil load present					
51874418	*Staphylococcus aureus* (ATCC 6538)	122108J5-LCL	1.00×10^1	99.99997%	7.53
		122109J5-LCL	1.00×10^1	99.99997%	
		122110J5-LCL	1.00×10^1	99.99997%	(3.41×10^7)
51874419	*Klebsiella aerogenes* (ATCC 13048)	122108J5-LCL	1.00×10^1	99.999901%	7.00
		122109J5-LCL	1.00×10^1	99.999901%	
		122110J5-LCL	1.00×10^1	99.999901%	(1.01×10^7)

Residual Sanitizer

MRID	Organism	Results			Population Control Average Log_{10} CFU/ carrier (Geometric Mean)
		Lot No.	Average Log_{10} CFU/ Carrier	Percent Reduction	
Ready-to-use trigger spray, 5 minutes, 5% soil load present					
51929701¥	*Staphylococcus aureus* (ATCC 6538)	122108J5-LCL	8.86×10^1	99.995%	6.23
		122109J5-LCL	4.79×10^1	99.997%	
		122110J5-LCL	1.51×10^1	99.991%	(1.71×10^6)
51929702ŧ	*Klebsiella aerogenes* (ATCC 13048)	122108J5-LCL	3.76×10^3	99.91%	6.62
		122109J5-LCL	2.23×10^3	99.95%	
		122110J5-LCL	1.71×10^3	99.96%	(4.16×10^6)

¥Abrasion/reinoculation procedures for MRID 51929701 were conducted on 2/21/2022, 2/22/2022, and 2/23/2022. The sanitization efficacy test was initiated on 2/24/2022.

ŧ Abrasion/reinoculation procedures for MRID 51929702 were conducted on 3/8/2022, 3/9/2022, and 3/10/2022. The sanitization efficacy test was initiated on 3/11/2022.

VI. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51874411, 51874412, 51874413, 51874414, 51874415	Disinfection, bactericidal	Hard, non-porous surface	Ready-to-use liquid trigger spray	9 minutes 30 seconds	5% FBS	N/A	• *Salmonella enterica* (ATCC 10708) • *Pseudomonas aeruginosa* (ATCC 15442) • *Staphylococcus aureus* (ATCC 6538) • *Escherichia coli* O157:H7 (ATCC 35150) • Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592)	**Yes**
51874416, 51874417	Disinfection, virucidal	Hard, non-porous surface	Ready-to-use liquid trigger spray	9 minutes 30 seconds	5% FBS	N/A	• Influenza A (H1N1) virus, A/PR/8/34 strain (ATCC VR-1469) • Human coronavirus, 229E strain (ATCC VR-740)	**Yes**
51874418, 51874419	Non-Food Contact Sanitizer	Hard, non-porous surface	Ready-to-use liquid trigger spray	4 minutes 30 seconds	5% FBS	N/A	• *Staphylococcus aureus* (ATCC 6538) • *Klebsiella aerogenes* (ATCC 13048)	**Yes**
51929701, 51929702	Residual Sanitizer	Hard, non-porous surface	Ready-to-use liquid trigger spray	5 minutes	5% FBS	N/A	• *Staphylococcus aureus* (ATCC 6538) • *Klebsiella aerogenes* (ATCC 13048)	**Yes**

VII. LABEL COMMENTS

Label Date: 6/3/2022

1. The proposed label claims that the product, Jaguar 5, EPA Reg. No. 92082-G**,** when applied as a ready-to-use trigger spray, is an effective disinfectant with bactericidal and virucidal activity against the following on visibly clean hard, non-porous surfaces for a 10-minute contact time:

   Salmonella enterica (ATCC 10708)
   Pseudomonas aeruginosa (ATCC 15442)
   Staphylococcus aureus (ATCC 6538)
   Escherichia coli O157:H7 (ATCC 35150)
   Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592)
   Influenza A (H1N1) virus, A/PR/8/34 strain (ATCC VR-1469)
   Human coronavirus, 229E strain (ATCC VR-740)

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Jaguar 5, EPA Reg. No. 92082-G**,** when applied as a ready-to-use trigger spray, is an effective non-food contact sanitizer with bactericidal activity against the following on visibly clean hard, non-porous surfaces a 5-minute contact time:

   Staphylococcus aureus (ATCC 6538)
   Klebsiella aerogenes (ATCC 13048)

   These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the product, Jaguar 5, EPA Reg. No. 92082-G**,** when applied as a ready-to-use trigger spray, is an effective residual sanitizer with bactericidal activity against the following on visibly clean hard, non-porous surfaces for a 5-minute contact time:

   Staphylococcus aureus (ATCC 6538)
   Klebsiella aerogenes (ATCC 13048)

   These claims are **acceptable** as they are supported by the submitted data.

4. Make the following changes to the proposed label:
   a. **Throughout the label,**
      i. **Remove all fungistatic, mildewstatic and/or mold and mildewcide claims** as data have not submitted to support these claims (i.e., “kills/controls fungi and mold). Alternatively, each instance on the label should specify “for odor-causing” or “for aesthetic purposes only”.
      ii. Remove the brackets from each instance of “24 hours” when referencing residual sanitizer claims.
      iii. **Remove all germ claims** or ensure that each instance of “germ(s)”, “germicide”, and “germicidal” is qualified appropriately according to the following guidance: https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels

iv. When referencing residual sanitizing claims, ensure that brackets are removed from “24 hours” and that each claim is qualified with “on treated hard, nonporous surfaces”.
v. Remove “protection” when referencing disinfection, non-food contact sanitizer as this is beyond the scope of the efficacy data. In addition, recommend revising each instance of “Continuous [24-hour] protection” to “24-hour residual sanitizer on treated hard, nonporous surfaces”.
vi. Remove “Microbial”, “Microbiocidal” and “Microbiostatic” as this language implies that the subject product is effective against all microbes.

b. On page 2, under “Directions for Use”, revise the use directions for “To Disinfect” and “To Sanitize” to include “Ensure all surfaces are visibly clean” prior to disinfecting or sanitizing.
c. On page 3,
    i. Revise “Compatible across a broad range of non-porous surfaces” to “Compatible on hard, nonporous surfaces specified on the label”.
    ii. Remove “Antiviral” as this language is misleading to end users. This may be revised to virucidal.
    iii. Remove “grade” from “Hospital[-grade] disinfectant”. Per the label review manual, this implies enhanced efficacy.
    iv. Qualify “One step cleaner and disinfectant” with “when applied according to the use directions for disinfection”.
    v. Revise “Reduces cross contamination on treated surfaces” to “Reduces cross contamination on treated **hard, nonporous** surfaces”.
d. On page 4,
    i. Remove “commonly” as this term is vague. Alternatively, revise “commonly” to ensure that the appropriate use sites or surfaces are specified when using this claim.
    ii. Revise “Can help reduce ~~the risk of~~ cross-contamination ~~from~~ treated surfaces” to “Can help reduce cross-contamination **between** treated surfaces”.
    iii. Remove “household” or alternatively, qualify “household” with the specific bacteria and surfaces listed on the label.
    iv. Remove “even after multiple touches” as this statement may be misleading to end users”.
    v. Recommend revising each instance of “24-hour Protection” to “24-hour residual sanitization”.
    vi. Revise “Long-lasting protection against bacteria” to “24-hour residual sanitizer against bacteria”.
e. On page 5, remove “Continuously active microbiostatic coating” and “Provides/creates an invisible barrier” as these statements are misleading to end users.
f. On pages 5 and 6, specify that “Appliances” be allowed to come to room temperature before treatment.
g. On pages 5 through 8, revise the table headers under “Use Sites” to specify “Hard, Non-Porous Surfaces”.
h. On page 6,
    i. Remove the brackets from “Bed[s] [frames]”, “Curtains [plastic or vinyl]”, " Diagnostic equipment [Hard] [Non-porous]”, “Mattresses [plastic or vinyl]”, “Walls [painted]”
    ii. Specify “Floors” with “sealed”.

iii. Remove Table 4 (header and surfaces/materials listed) as “Microbiostatic” implies that the subject product is effective against all microbes.

i. On page 8, each symbol, especially the “24-hour symbol” should be revised to specify “residual sanitizer”.